

REMARKS

The office action dated June 13, 2006 (the "Office Action") has been received and noted. Claims 1, 3, 5-8, 19-22 and 63-68 were examined. Claims 1, 3, 5-8, 19-22 and 63-68 were rejected. Claims 1, 3, 5, 8, 19, 20 and 68 are amended. Claims 69-72 are new. Support for the amended claims can be found in, for example, paragraphs [0070], [0091], [0127] and [0100] of the Application. Support for the new claims can be found in, for example, paragraph [0127] of the Application. As such, no new matter has been added. Reconsider of the claims is respectfully requested in view of the above-amendments and subsequent remarks.

I. Claims Rejected Under 35 U.S.C. § 112

Claims 19-22, 63-65, 67 and 68 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Amendments which (1) merely clarify or make definite that which an originally-filed application expressly or inherently discloses, or (2) conform the specification to the originally disclosed drawings or claims, do not violate the rule of new matter. Thus, "insertions by way of amendment in the description or drawing, or both, of a patent application do not invalidate the patent, if they are only in amplification and explanation of what was already reasonably indicated to be within the invention." *Michigan Carter Co. v. Sutherland Paper Co.*, 29 F.2d 179, 184 (6th Cir. 1928). Moreover, a new matter rejection is only proper if the amendment is wholly unsupported subject matter. MPEP § 706.03(o). Applicants respectfully submit that independent claim 19 is merely an amplification and explanation of the originally-filed Application and is wholly supported by the originally-filed Application.

Independent claim 19 includes the limitation of "applying a pacing therapy to the ventricle to pre-excite the infarct region to contract during systole at a time before contraction of the ventricle initiated by the His Purkinje conduction network." This limitation is at least supported in the Application by paragraph [0070], which states in pertinent part, "[i]n one embodiment, electrostimulatory pacing pulses may be delivered to one or more sites in or around the infarct in a manner that pre-excites those sites relative to the rest of the ventricle." (App., ¶ [0070]) It is well known by those skilled in the art that the specialized His-Purkinje conduction

network of the heart rapidly conducts excitatory impulses from the sinoatrial node to the atrio-ventricular node and results in the contraction of the ventricles during systole.

It is well known that the human heart consists of four chambers, the right and left atria and the right and left ventricles. The right atrium is separated from the right ventricle by the tricuspid valve and the left atrium is separated from the left ventricle by the mitral valve. As blood collects in the right and left atria, the SA node sends out an electrical signal that causes the atria to contract. This contraction pushes bloods through the tricuspid and mitral valves into the right and left ventricles. This process is known as *diastole*. When the ventricles are full of blood, the electrical signals from the SA node travel to the His-Purkinje conduction network via the AV node causing the ventricles to contract. The tricuspid and mitral valves close and blood is pushed through the pulmonary and aortic valves. This process is known as *systole*. It is well known by those skilled in the art how the heart functions.

Thus, by definition, the excitatory signals from the His-Purkinje network inherently are released during systole since the His-Purkinje conduction network is physically associated with the ventricles only (and not the atria) and functions only during systole. Therefore, in order for a portion of the ventricle to be “pre-excited” before being naturally excited by the His-Purkinje conduction network, the “pre-excitement” must take place during systole and before the His-Purkinje conduction network naturally sends out excitatory pulses. As such, the limitation in independent claim 19 is merely an amplification and explanation of the originally-filed Application and is wholly supported by the originally-filed Application. Accordingly, Applicants respectfully respect that the rejection be withdrawn.

II. Claims Rejected Under 35 U.S.C. § 112

Claims 1, 3, 5-8, 19-22 and 63-68 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1

The Examiner rejects the preamble of independent claim 1. Applicants respectfully submit that section 112 does not require Applicants to state anything more than “a method comprising” in the preamble. The elements of a claim, rather than the preamble, define the invention and the preamble is not construed into a claim unless it (a) recites a limitation of the claim or (b) is necessary to give life, meaning and vitality to the claim. MPEP 2111.02. A basic search on the USPTO website from 1974 to the present cites no less than 379,457 patents which include the preamble “a method comprising” and nothing more. Moreover, courts have stated that “a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention.” *Catalina Marketing International Inc. v. Coolsavings.com, Inc.*, 62 U.S.P.Q.2d 1781, 1785 (Fed. Cir. 2002). Although the issue is not whether the preamble is limiting in this case, the law as stated by the Federal Circuit is nonetheless applicable because the preamble in independent claim 1 does not affect the structure or steps of the claimed invention. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Examiner has stated that the limitation of “wherein the knock-out swine cells do not express a-1,3-galactosyltransferase” in claim 1 renders the claim indefinite. Appropriate correction has been made. (see App., amended claim 1) Accordingly, Applicants respectfully request withdrawal of the rejection.

The Examiner has stated that the limitation “stimulate a beneficial response” renders claim 1 indefinite. Applicants respectfully remind the Examiner that breadth of a claim is not to be equated with indefiniteness. MPEP 2173.04. Moreover, one skilled in the art would understand that a beneficial response could mean, without limitation thereto: replacement of myocardial cells; reinforcement of an infarct region; or prevention of the thinning process in the infarct region. (see, e.g., App., ¶ [0028]) Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 3

The Examiner has stated that there is insufficient antecedent basis for “the donor cells” and that “a donor cell” in line 3 is unclear. Appropriate correction has been made. (see App., amended claim 1) Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 5

The Examiner has stated that there is insufficient antecedent basis for “donor cells.” Appropriate correction has been made. (see App., amended claim 1) The Examiner has stated that an “amount” to “structurally reinforce the infarct region” renders the claim indefinite. Amended claim 5 includes the limitation of “an effective amount” and “wherein the effective amount is in a range of between 1 μ L and 1 mL.” Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 6

The Examiner has stated that there is insufficient antecedent basis for “donor cells.” Appropriate correction has been made. (see App., amended claim 1) Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 7

The Examiner has stated that there is insufficient antecedent basis for “donor cells.” Appropriate correction has been made. (see App., amended claim 1) Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 8

The Examiner has stated that there is insufficient antecedent basis for “donor cells.” Appropriate correction has been made. (see App., amended claim 1) Moreover, the Examiner has stated that claim 8 remains awkward. Claim 8 has been amended to “an expression vector comprising the donor cells comprise complementary DNA encoding a detectable polypeptide that is operably linked to a promoter.” Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 67

The Examiner has stated that there is insufficient antecedent basis for “donor cells.” Appropriate correction has been made. (See App., amended claim 1) Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 19

The Examiner rejects the preamble of independent claim 19. Applicants respectfully request the rejection to be withdrawn in accordance with the argument submitted with respect to claim 1 above.

The Examiner states that the phrase “structurally reinforcing component” renders claim 19 indefinite. Claim 19 has been amended to “percutaneously delivering at least one immunotolerant cell line to the infarct region after applying the pacing therapy.” Accordingly, Applicants respectfully request withdrawal of the rejection.

Regarding the Examiner’s statement that the article “an” is inappropriate at the fourth line of claim 19, Applicants respectfully bring to the Examiner’s attention that this article was (and remains) deleted in claim 19. Moreover, the phrase “unload the infarct region from mechanical stress” was (and remains) similarly deleted.

Claim 22

The Examiner states that the phrase “sensed measurement” renders claim 22 indefinite. Applicants respectfully remind the Examiner that breadth of a claim is not to be equated with indefiniteness. MPEP 2173.04. Moreover, one skilled in the art would understand that sensed measurement could mean, without limitation thereto: wall motion during the cardiac cycle; impedance signals from a paced region and a non-ischemic region; or a change in a wall thickness of a paced region. (see, e.g., App., claims 63-65, ¶ [0082]) In addition, one skilled in the art would understand that “modifying” could mean, without limitation thereto, increasing or reducing the pacing. (see, e.g., App., claim 69, ¶ [0082]) Accordingly, Applicants respectfully request withdrawal of the rejection

Claim 67

The Examiner has stated that there is insufficient antecedent basis for “donor cells.” Appropriate correction has been made. (see App., amended claim 1) Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 68

The Examiner states that the phrase “healing response” renders claim 68 indefinite. Applicants respectfully remind the Examiner that breadth of a claim is not to be equated with indefiniteness. MPEP 2173.04. Moreover, one skilled in the art would understand that a “healing response” could mean, without limitation thereto: replacement of myocardial cells; reinforcement of an infarct region; or prevention of the thinning process in the infarct region. (see, e.g., App., ¶ [0028]) Accordingly, Applicants respectfully request withdrawal of the rejection.

III. Claims Rejected Under 35 U.S.C. § 103

A. Response to rejections

Claims 1, 3, 5-8 and 66 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,919,449 to Dinsmore (“*Dinsmore*”) in view of U.S. Patent No. 6,153,428 to Gustafsson, et al. (“*Gustafsson*”) in further view of Circulation, 2002 to Strauer (“*Strauer*”) and J. Mol Cell Cardiol, 2001 to Etzion et al. (“*Etzion*”). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

More particularly, the references when combined do not teach or suggest all of the claim limitations of amended independent claim 1. Amended independent claim 1 includes the limitation of “applying a pacing therapy to the ventricle to pre-excite the infarct region to contract during systole at a time before contraction of the ventricle initiated by the His Purkinje

conduction network.” *Dinsmore* describes non-genetically altered modified porcine cardiomyocytes to treat disorders characterized by insufficient cardiac function. (Abstract) *Gustafsson* describes generally α -(1,3) galactosyltransferase negative porcine cells for xenotransplantation. (col. 2, lns. 19-24) *Strauer* describes the use of bone marrow cells to regenerate infarcted myocardium and inducing myogenesis and angiogenesis. (p.1913, col. 2) *Etzion* describes non-genetically altered embryonic cardiomyocytes for the reduction of infarct expansion, left ventricular dilatation and heart failure progression. (p.1322, col. 1) However, none of the cited references teach or suggest applying a pacing therapy to the ventricle to pre-excite the infarct region to contract during systole at a time before contraction of the ventricle initiated by the His Purkinje conduction network before application of any of these treatments. Dependent claims 3, 5-8 and 66 are dependent on independent claim 1 and therefore include all of its limitations. Accordingly, Applicants respectfully submit that independent claim 1 and its respective dependent claims are allowable over the cited references.

B. Statement of common ownership under 35 U.S.C. § 103(c) pursuant to MPEP 706.02(I)(2)

Claims 19-22 and 63-68 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Pub. No. 2003/0105493 to Salo (“*Salo*”) in view of *Dinsmore* in further view of *Gustafsson*. In response, Applicants state the following:

U.S. Patent Application No. 10/802,955 by Michal et al. and U.S. Patent Publication No. 2003/0105493 by Salo were, at the time the invention of U.S. Patent Application No. 10/802,955 was made, owned by Guidant Corporation.

This statement alone is sufficient evidence to disqualify U.S. Patent Publication No. 2003/0105493 from being used in a rejection under 35 U.S.C. § 103(a) against the claims of U.S. Patent Application No. 10/802,955 because the Applicants and/or the representatives of the record have the best knowledge of the ownership of their Application and references, and their statement of such is sufficient evidence due to their paramount obligation of candor and good faith to the USPTO. MPEP 706.02(I)(2)(II). The Examiner has not stated that she has independent evidence that raises a material doubt as to the accuracy of Applicants’

representation. *Id.* Accordingly, Applicants respectfully request that the rejection based on the primary reference of *Salo* be withdrawn.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 500-4787.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: 8/22, 2006


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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage thereon in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, Post Office Box 1450, Alexandria, Virginia 22313-1450, on 8-22-06 2006.

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Melissa Stead mm 2006